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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,567	11/14/2003	Paul Wentworth	1361.028US1	1768

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EXAMINER	
VENCI, DAVID J	

ART UNIT	PAPER NUMBER
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/714,567	WENTWORTH ET AL.	
	Examiner	Art Unit	
	David J. Venci	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *January 3, 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-13 and 15-44* is/are pending in the application.

4a) Of the above claim(s) *21-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 5-13 and 15-20* is/are rejected.

7)☒ Claim(s) *5,6,15 and 16* is/are objected to.

8)☒ Claim(s) *1-3,5-13 and 15-44* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges Applicants' reply filed January 3, 2007. Applicants' amendment to claim 11 and related argumentation in support for rejoinder of withdrawn claims 11-13 and 15-20 are persuasive. Herein, Examiner rejoins claims 11-13 and 15-20.

Claims 21-44 are directed to a non-elected invention and were withdrawn from consideration pursuant to 37 CFR 1.142(b) in the Office Action dated May 25, 2005.

Currently, claims 1-3, 5-13 and 15-20 are under examination.

Specification

The disclosure is objected to because of the following informalities:

- Throughout the specification, reference to the conversion of "singlet oxygen" into "reactive oxygen species" appears repugnant to the art-recognized definition of "reactive oxygen species" because persons skilled in the art generally do not recognize "singlet oxygen" as a separate genus, but rather recognize that "singlet oxygen" belongs to the broader genus of "reactive oxygen species." Furthermore:

  On p. 24, lines 27-28, the phrase "[t]he role of the newly discovered chemical potential of antibodies [to generate reactive oxygen species] *in vivo* is dependent on the availability of the key substrate $^1O_2$*" (paraphrasing mine) is indefinite in view of p. 18, lines 4-5 phrase "the term 'reactive oxygen species' means antibody-generated oxygen species".

On p. 30, line 13, the phrase "[i]n the present invention, the minimum requirements are singlet oxygen, an antibody reagent..." (paraphrasing mine) is indefinite in view of p. 18, lines 4-5 phrase "the term 'reactive oxygen species' means antibody-generated oxygen species".

Appropriate correction is required.

Claim Objections

Claims 5, 6, 15 and 16 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Specifically, claims 5, 6, 15 and 16 recite various compounds that do not materially alter performance of any step recited in base claims 1 and 11. Applicants are required to cancel the claims, amend the claims into proper dependent form, or rewrite the claims in independent form.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 5-13 and 15-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the claim preamble does not correspond to the method outcome. Specifically, whether/how merely detecting a "probe" in step (c) amounts to a method of detecting an "immunological response" is not clear. Whether the object(s) and/or step(s) required for detecting a "probe" are coextensive with the objects and/or steps required for detecting an "immunological response" is not clear. The object(s) and/or step(s) pertaining to detecting an "immunological response" appear omitted from claim 1.

In claim 11, the claim preamble does not correspond to the method outcome. Specifically, whether/how merely detecting a "probe" in step (c) amounts to a method of detecting an "inflammatory response" is not clear. How the object(s) and/or step(s) required for detecting a "probe" are coextensive with the objects and/or steps required for detecting an "inflammatory response" is not clear. The object(s) and/or step(s) pertaining to detecting an "inflammatory response" appear omitted from claim 1.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 5-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Iribarren *et al.*, 17 ARTERIOSCLER. THROMB. VASC. BIOL. 1171 (1997).

Iribarren *et al.* describe a method for detecting an immune response in a mammal comprising:

(a) administering a chemical probe (see p. 1172, right column, *Dietary Intake of Vitamins*) for[1] reactive oxygen;

(b) obtaining a sample from the mammal (see p. 1172, *Autoantibodies to Modified LDL*, sixth sentence, "serum"); and

(c) detecting an oxidized chemical probe thereby detecting an immune response (see p. 1172, right column, *Autoantibodies to Modified LDL*, fourth sentence; *see also*, p. 1175, paragraph bridging left and right columns, first sentence, "no significant cross-sectional relation was observed between autoantibodies against MDA-LDL and IMT").

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[1] Examiner posits that Iribarren *et al.* describe chemical probes (*i.e.*, vitamins) that are inherently "for" reactive oxygen species, including superoxide radicals, hydroxyl radicals, peroxyl radicals, hydrogen peroxide and ozone. Persons of ordinary skill recognize that vitamins are inherently "for" the aforementioned reactive oxygen species. See *e.g.*, Palozza & Krinsky, 213 METHODS ENZYMOL. 403 (1992), *noting* in the second paragraph that antioxidants deactivate peroxyl radicals.

Claims 1-3, 5-13 and 15-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Medford et al. (US 5,846,959).

Medford *et al.* describe a method for detecting an immune response in a mammal comprising:

(a) administering a chemical probe (see col. 4, lines 36-39, "administration of an appropriate antioxidant", see col. 4, lines 48-54, "administering to a host animal an excessive amount of PUFA or oxidized polyunsaturated fatty acid") for[2] reactive oxygen;

(b) obtaining a sample from the mammal (see col. 4, lines 28-35, "tissue or blood"); and

(c) detecting an oxidized chemical probe thereby detecting an immune/inflammatory response (see col. 4, lines 28-35, "the level of oxidized polyunsaturated fatty acid, or other appropriate markers... is evaluated"; *see also*, col. 4, lines 48-54, "in vivo models of... inflammatory diseases... can be provided").

With respect to claims 2-3 and 12-13, Medford et al. describe a method comprising cholesterol (see Example 14).

With respect to claims 9 and 19, Medford et al. describe a tissue sample (see Example 14).

With respect to claims 10 and 20, Medford et al. describe UV spectrophotometry detection (see Example 16).

[2] Examiner posits that Medford *et al.* describe chemical probes (*i.e.*, antioxidants) that are inherently "for" reactive oxygen species, including superoxide radicals, hydroxyl radicals, peroxyl radicals, hydrogen peroxide and ozone. Persons of ordinary skill recognize that antioxidants are inherently "for" the aforementioned reactive oxygen species. See *e.g.*, Palozza & Krinsky, 213 METHODS ENZYMOL. 403 (1992), *noting* in the second paragraph that antioxidants deactivate peroxyl radicals.

Response to Arguments

In prior Office Action, claims 1-3 and 5-10 were rejected under 35 U.S.C. 102(b) as being anticipated by Iribarren *et al.*, 17 ARTERIOSCLER. THROMB. VASC. BIOL. 1171 (1997).

In response, Applicants amend independent claims 1 and 11 to require a chemical probe for superoxide radical, hydroxyl radical, peroxyl radical, hydrogen peroxide and ozone.

Applicants' amendment and related argumentation are not sufficient to overcome this rejection for the reasons set forth in note 1.

Conclusion

No claims are allowable at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

David J Venci
Examiner
Art Unit 1641

djv

LONG V. LE 02/28/07
SUPERVISORY PATENT EXAMINER
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